How many well-baby visits are necessary in the first 2 years of life?

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Since we could find no scientific basis for the 10 well-baby visits recommended in the first 2 years of life in Ontario, we carried out a randomized trial in 570 healthy, low-risk newborns to determine the efficacy and safety of decreasing the number of scheduled well-baby visits from 10 to 5. Among the 466 babies still in the trial at the end of the study period those in the 10-visit group had had a mean of 7.63 scheduled and 0.26 unscheduled well-baby visits and those in the 5-visit group a mean of 4.77 scheduled and 1.42 unscheduled well-baby visits. Reducing the recommended number of visits did not result in an increased incidence of illness or an increased prevalence of undetected abnormality, and the physical development of the babies in the two groups was almost identical. The mean scores of the two groups in assessments of mental development, maternal–child relations, maternal anxiety and parental satisfaction with health care were close. The results suggest that the recommended number of well-baby visits for healthy, low-risk newborns can be reduced to five for children of multiparas and six for children of primiparas. Any additional well-baby visits should be scheduled according to the needs and experience of the parents.

N'ayant pu trouver de fondement scientifique des 10 consultations pédiatriques de dépistage recommandées en Ontario au cours des 2 premières années de la vie, nous avons mené un essai randomisé chez 570 nouveau-nés en bonne santé et à faible risque visant à établir la sûreté et l'efficacité de réduire le nombre des consultations pédiatriques de dépistage prévues de 10 à 5. Parmi les 466 bébés qui faisaient encore partie des effectifs à la fin de l'étude, ceux du groupe de 10 consultations avaient eu en moyenne 7,63 consultations de dépistage prévues et 0,26 consultations de dépistage non prévues; pour le groupe de 5 consultations les chiffres correspondants étaient de 4,77 et 1,42 consultations respectivement. Le fait de réduire le nombre recommandé de consultations n'a pas entraîné une augmentation de l'incidence des maladies ou de la prévalence des anomalies passant inaperçues. De plus, le développement physique des bébés des deux groupes a été presque identique. Les cotes moyennes chez les deux groupes des mesures du développement mental, des relations mère–enfant, de l'anxiété maternelle et de la satisfaction des parents à l'égard des soins de santé étaient semblables. Ces résultats montrent que le nombre recommandé de consultations pédiatriques de dépistage chez les nouveau-nés en bonne santé et à faible risque pourrait être réduit à cinq pour les enfants de multipares et à six pour les enfants de primipares. Toute consultation additionnelle de dépistage devrait être organisée en fonction des besoins et de l'expérience des parents.

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Well-baby visits have four major purposes: screening for physical disease, screening for disturbances in child–parent relations, immunization and health counselling. The frequency of these visits (Table I), who provides them and what actually occurs during them all vary from country to country. In addition, recommendations as to frequency change over time. In 1977 the American Academy of Pediatrics recommended eight visits over 2 years,[4] but it recently proposed a 50% increase in the number of visits for well children aged 1 month to 21 years.[5] In Ontario in 1980 the pro-

Table I—Number of well-baby visits currently recommended in the first 2 years of life

Country or region	No. of visits recommended: First year of life	Second year of life
Belgium[1]	15	0
Canada[2]	6	3
Finland[3]	12	0
France[1]	9	6
Holland[1]	8–12	0
United Kingdom[3]	12	4
United States[4]	6	4

vincial government paid for a maximum of 10 well-baby visits during the first 2 years of life; more recently this upper limit has been removed. The Canadian Paediatric Society recommends nine visits over 2 years.[2] In 1980 we surveyed 180 randomly selected family physicians in Ontario and found that they scheduled a mean of 9.3 visits over 2 years.[6]

It is not known how many parents comply with these recommendations or whether they need to do so. For example, Hoekelman[7] reported no differences in outcome of three versus six well-baby visits in the first year of life. However, this study included two additional visits for immunizations, and additional screening and counselling may have occurred during these visits. Thus, Yankauer's[8] plea for prospective study of this question still stands.

Since we could find no scientific basis for the 10 well-baby visits allowed in Ontario in 1980 we carried out a randomized trial to determine the efficacy and safety of decreasing the recommended number of scheduled well-baby visits in the first 2 years of life from 10 to 5. The number 5 was chosen as the minimum number of visits needed to complete the necessary immunizations.

Methods

Criteria for inclusion

A newborn from a participating family practice was eligible for the trial if the following criteria were met:

- The baby's weight at birth was over 2500 g.
- The baby was discharged from hospital within 7 days of birth (except when the stay was extended for maternal reasons, such as cesarean section).
- The baby was signed out as "normal" by the attending physician.
- The mother's age was between 18 and 40 years.
- The mother previously had delivered no more than five living babies.
- The parents were living together at the time of delivery.
- The family was expected to remain in the study area for at least 2 years.

Mothers of eligible newborns were informed about the trial and were invited to participate.

Maneuver

Babies of consenting mothers were randomly assigned by a research assistant to one of two groups, one to have 5 well-baby visits in the first 2 years of life and one to have 10. For the 5-visit group the first visit could be paid when the baby was either 1 or 2 months of age, with the remaining 4 visits scheduled at 4, 6, 13 and 19 months of age; the 10-visit group had well-baby visits scheduled at 2 weeks of age and then at 1, 2, 4, 6, 10, 12, 15, 18 and 24 months of age. Both groups had free access to additional visits for any reason.

Follow-up

Each baby was followed up for 2 years, during which time the family physician's chart was regularly reviewed for well-baby visits, and utilization of other health care services was monitored. The charts were reviewed when the babies were 2, 12, 18 and 24 months of age by research assistants who were unaware of the babies' group assignments and used standardized criteria. Each visit was classified into one of four categories:

- Ill-baby visit (an intercurrent illness was diagnosed or treated, or both).
- Scheduled well-baby visit (the timing of the visit coincided with the recommended schedule, and no intercurrent illness was diagnosed or treated).
- Unscheduled well-baby visit (the timing of the visit did not coincide with the recommended schedule, yet no intercurrent illness was diagnosed or treated, nor was any immunization given).*
- Indeterminate visit (the visit satisfied none of the foregoing criteria).

The duration of each well-baby visit to a subset of the family physicians was also recorded by the office receptionists. In addition, all illnesses and abnormalities noted in the chart were recorded on a chart review form, and two physicians unaware of the babies' group assignments independently classified each as "major" (if the condition was treatable and, if not diagnosed at an appropriate age, could lead to long-term physical and emotional sequelae) or "minor" (if otherwise). Thus, strabismus diagnosed in a baby older than 6 months and deformities of the feet or hips that required the use of splints, braces or casts were considered major abnormalities.*

Parent-initiated utilization was monitored to document total utilization of health care services by both the 5-visit and 10-visit groups: ill-baby contacts (office visits, house calls, consultations, admission to hospital and emergency room visits) for all babies, plus telephone calls from parents to a subset of the family physicians, were noted.

An assessment of the babies was carried out when they were between 24 and 27 months of age. This assessment consisted of a standardized physical examination done by an independent pediatrician who was unaware of the babies' group assignments, and a battery of tests administered in a home visit by study staff who were unaware of the babies' group assignments. These tests included the following:

- The Mental Development Index of the Bayley scales of infant development[9] (to identify previously undetected developmental problems).
- The Home Observation for Measurement of the Environment test[10] (to assess the physical organization and safety of the home, the availability of toys and other play materials, and the degree of maternal involvement with the child).
- The Hulka Infancy Questionnaire[11] (to assess maternal anxiety).
- A standardized questionnaire developed by Hulka to assess parental satisfaction with health care.[12,13]

Sample size and statistical analysis

The number of babies to be included in this trial was determined on the basis of both pragmatic and scientific requirements; we took into consideration both the logistics of

*A list of all the major and minor conditions is available from the authors.

how many babies could be entered during a 1-year period and followed up for 2 years, and the number of babies required to detect what we considered a clinically important difference between the two groups in the proportions of babies with abnormalities. Assuming on the basis of our clinical experience that 20% of the babies in the 10-visit group would be found to have abnormalities at the end of the trial, we would need to detect abnormalities in 33% of the babies in the 5-visit group. Setting the risk of both type I (false-positive) and type II (false-negative) errors at 0.05, we determined that 250 babies were required in each group.

This sample size was more than enough to enable us to detect (with a power of at least 95%) clinically significant differences in the other outcomes of interest. Both baseline comparability and outcomes of the two groups were assessed by the chi-square test and by the *t*-test. Multiple regression analysis was used to determine the influence of family size, maternal age, parity and socioeconomic status on the number of visits made to physicians and other sources of health care.

Study population

The study began in May 1979, and enrolment was completed by May 31, 1980. Twenty-six practices in southwestern Ontario participated, and 570 newborns were consecutively enrolled from four regional hospitals within a week of birth. The number of babies from each practice ranged from 3 to 80, with a mean of 21.9. Of the 570 babies 269 were assigned to the 5-visit group and 301 to the 10-visit group; each practice had an approximately equal number of babies in each group. The refusal rate was 6%.

Results

Table II compares the baseline characteristics of the two groups. None of the differences between the two groups in these characteristics was statistically significant, although the difference in the percentage of cesarean births approached significance ($p = 0.056$). Of the 570 babies the study was completed for 466 (82%); for 20 patients in the 5-visit group and 17 in the 10-visit group there was a change of family physician during the study period, but the new physician agreed to complete the research protocol. Reasons for withdrawal from the study were similar for the 5-visit and 10-visit groups (Table III). Fifteen patients (5.6%) in the 5-visit group, as compared with seven (2.3%) in the 10-visit group, were withdrawn because of the parents' unwillingness to continue with the study; however, this difference was not statistically significant. Five patients in each group were lost to follow-up.

Visits

Visits to the family physician and other sources of health care are summarized in Table IV. The patients in the 5-visit group had a mean of 6.19 well-baby visits, and those in the 10-visit group 7.89. Most of the unscheduled well-baby visits in the 5-visit group occurred in the first month of life. There were neither clinically nor statistically significant differences between the two groups in the use of consultants or emergency rooms or in the frequency of admission to hospital.

For both the 5-visit and 10-visit groups there was a statistically significant inverse relation between the number of children in the family and the number of well-baby visits (scheduled and unscheduled) in that primiparas made more visits. There was no significant relation, however, between the number of visits and the mother's age or parity or the socioeconomic status of the family.

The mean duration of the well-baby visit at 2 months of age was 11.2 minutes for the 5-visit group

Table II—Baseline characteristics of 5-visit and 10-visit groups of newborns in southwestern Ontario

Characteristic	5-visit group (n = 269)	10-visit group (n = 301)
Sex, no. of newborns		
Male	129	146
Female	140	155
Mean weight at birth, kg	3.47	3.53
Mean age of mother, yr	27.3	26.9
Mean no. of living children in family	1.88	1.75
Obstetric status, no. of mothers		
Primiparous	110	135
Multiparous	159	166
Socioeconomic status, no. of families		
Upper 50%	137	146
Lower 50%	132	155
Cesarean births, %	15.2	9.6
Infants breast-fed, %	70.9	71.1
Families visited by public health nurse, %	65.6	64.4

Table III—Reasons for withdrawal from the study*

Reason	No. of withdrawals: 5-visit group (n = 50)	10-visit group (n = 44)
Move of family from area	22	22
Unwillingness to continue	15	7
Change to pediatrician	6	8
Change of family physician	7	5
Death of infant	0	2

*Five patients in each group were lost to follow-up.

Table IV—Mean number of visits to family physicians and other sources of health care

Source of health care; category of visit	Mean no. of visits: 5-visit group (n = 214)	10-visit group (n = 252)
Family physician	12.49	14.48
Scheduled well-baby	4.77	7.63
Unscheduled well-baby	1.42	0.26
Ill-baby	6.09	6.54
Indeterminate	0.21	0.05
Consultants	1.25	1.15
Emergency room	0.88	0.93
Hospital	0.08	0.11

and 10.0 minutes for the 10-visit group. There was no statistically significant difference between the two groups in the mothers' perception of the duration.

The first time the parents were asked whether they had telephoned their physician in the past week 34 mothers in the 5-visit group and 40 in the 10-visit group reported having made such calls regarding their babies. The second time this question was asked the numbers of mothers were 28 and 29 respectively. The number of telephone calls made by the parents during the study period had been recorded by the receptionists of a subsample of the family physicians. The mothers in the 5-visit group had made a mean of 2.1 calls and the mothers in the 10-visit group 2.0.

Demand by the two groups for services by consultants, at emergency rooms, on the telephone, in hospital or in the physician's office was similar. There was no difference between the two groups in the amount of time spent at the well-baby visit in the office.

Outcomes

The study pediatrician, who was unaware of the group assignments of the babies, did a complete physical examination of the babies at the end of the study and found major abnormalities in 10 (4.7%) of those in the 5-visit group and in 16 (6.4%) of those in the 10-visit group. The 95% confidence interval for the absolute difference between these rates ranged from 2.7% more in the 5-visit group to 5.8% more in the 10-visit group. Minor abnormalities were found in 30.2% of the babies in the 5-visit group and in 29.2% of those in the 10-visit group. The corresponding confidence interval ranged from 9.5% more in the 5-visit group to 7.4% less in the 10-visit group. All of these findings had already been documented in the patients' charts by their family physicians.

The nutritional status of the babies in the two groups at 2 years of age was identical. The mean weight (± the standard deviation) of those in the 5-visit and 10-visit groups was 12.6 ± 1.6 kg and 12.5 ± 1.4 kg respectively. The mean height of the babies at 2 years of age was 87.2 ± 3.3 cm for both groups. The mean head circumference of the babies was 49.4 cm and 49.0 cm for the 5-visit and 10-visit groups respectively. The mean weights, heights and head circumferences were all in the 50th percentile. At the time of discharge from hospital 71% of the babies in both groups were being breast-fed. We did not record duration of breast-feeding.

The immunization records of the two groups were identical.

The results of the assessments at the patients' homes at the end of the study are summarized in Table V. There were no statistically significant differences between the 5-visit and 10-visit groups in any of the scores.

From the parents' perspective, inconveniences related to the number of visits were insignificant. This likely reflects both the willingness of physicians to schedule appointments at times convenient to working mothers and the existence of a good support network of family and friends. The two fewer visits of the five-visit group represent a significant economic saving in a fee-for-service system.

Discussion

We had expected a major difference between the two groups in the total number of visits in the 2 years. However, the 10-visit group averaged only two more visits than the 5-visit group (14.48 v. 12.49), largely because the former averaged only 7.63 of the scheduled 10 well-baby visits. A further narrowing occurred as a result of the greater mean number of additional, unscheduled well-baby visits in the 5-visit group (1.42, v. 0.26 for the 10-visit group). There was a strong relation between the number of unscheduled visits and the number of children in the family in that primiparas more frequently made such visits.

Reducing the recommended number of well-baby visits in the first 2 years of life to five did not result in an increased incidence of illness or an increased prevalence of undetected abnormality. The physical development of the babies in the 5-visit and 10-visit groups was almost identical. The mean scores of the two groups in the assessments of mental development, maternal–child relations, maternal anxiety and parental satisfaction with health care were close.

This study was not designed to assess the number of well-baby visits appropriate for high-risk groups, such as infants of unwed mothers and infants with perinatal problems. However, the results suggest that for healthy, low-risk infants of multiparas the recommended number of well-baby visits can be reduced from 10 to 5 with no loss of efficacy or safety. For infants of primiparas there should be a sixth visit sometime in the first month of life.

In conclusion, the recommended number of well-baby visits in the first 2 years of life for healthy, low-risk newborns can be reduced to five for children of multiparas and six for children of primiparas. Any additional well-baby visits should be scheduled according to the needs and experience of the parents.

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Table V—Patients' scores in end-of-study assessments at their homes

Assessment tool	Mean score ± standard deviation: 5-visit group	Mean score ± standard deviation: 10-visit group
Mental Development Index[9]	124.1 ± 17.2	121.6 ± 17.8
Home Observation for Measurement of the Environment test[10]	40.0 ± 2.5	40.5 ± 3.0
Hulka Infancy Questionnaire[11]	13.7 ± 1.2	13.8 ± 1.6
Questionnaire to assess parental satisfaction with health care[12,13]	1.25 ± 0.69	1.27 ± 0.65

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